GE Healthcare

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Certified Mail Return Receipt Requested

Important Electronic Product Radiation Warning

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVANT SYSTEM(S) OF THESE ISSUES AND HOW TO ADDRESS THEM

April 2, 2007

To:	**Hospital Administrator**
	Director/Manager of Radiology
Subject:	**Product Safety Issues**
Affected Products:	**OEC® 9900 Elite** **OEC® 9800** **OEC® 8800** **OEC® 6800** **OEC® 2800**

Our records indicate that your facility has one or more of the products listed above.

GE Healthcare has identified an issue affecting the OEC® 9900 Elite, OEC® 9800, OEC® 8800, OEC® 6800, OEC® 2800.

A configuration issue has been discovered that results in the failure of the above listed systems to display the US Standard quantity air kerma as required to describe the radiation output for systems manufactured after June 10, 2006 by 21 CFR 1020.32(k).

For the 9800, 8800, 6800 and 2800 products the Air Kerma and DAP can both be displayed at the same time if properly configured. If not configured correctly, these products will only show the DAP calculation. The 9900 product can only display one value or the other. When the 9900 system is incorrectly configured Air Kerma is not displayed, however, the DAP is.

This issue does not affect the safe operation of your system, however, it does result in your system not being in compliance with 21 CFR 1020.32(k).

Your GEHC OEC service representative will be contacting you in the near future to arrange for an inspection to determine if the issue affects your system and will correct the configuration settings if needed at that time at no charge.

If you have any questions or concerns regarding these issues, please do not hesitate to contact the GEHC OEC service team for further information at 800-874-7378 option 8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,

Pete McCabe
President and CEO